

REMARKS

The above amendments and these remarks are responsive to the Office action dated January 4, 2006. Claims 1-11 and 13-25 are pending in the application. Claims 1-11 and 13-25 are rejected. By way of the present amendment, claims 1, 11 and 18 have been amended, claims 22 and 25 have been canceled, and new claims 26-28 have been added. In view of the amendments above, and the remarks below, Applicant respectfully requests reconsideration of the application under 37 C.F.R. § 1.111 and allowance of the pending claims.

Rejections under 35 USC §§ 102 and 103

Claims 1 and its Respective Dependent Claims

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Micro-Heart (WIPO publication WO 00/72908). Claims 2-6, 21 and 23, which depend directly or indirectly from claim 1, stand rejected under 35 U.S.C. § 102(b) based on Micro-Heart. Claim 7, which depends from claim 1, stands rejected under 35 U.S.C. § 103(a) based on Micro-Heart. Claims 8-10, which depend directly or indirectly from claim 1, stand rejected under 35 U.S.C. § 103(a) based on Micro-Heart in view of Paskar (U.S. Patent No. 6,623,449). Applicant disagrees with the rejections but has nonetheless made certain claim amendments to clarify what Applicant regards as the invention.

Amongst other structure, amended claim 1 recites at least one injection orifice on a sidewall of the end effector wherein the at least one injection orifice is oriented generally

laterally to the longitudinal axis of the end effector.

In contrast, Micro-Heart does not disclose, teach, or suggest a device having at least one injection orifice on a sidewall of the end effector wherein the at least one injection orifice is oriented generally laterally to the longitudinal axis of the end effector, as recited in amended claim 1. Instead, Micro-Heart discloses outlet ports or orifices 28a-28d on the distal end face, as shown in Figs. 2A-4 and 9A-9D and described on page 10 at lines 23-33. In particular, the outlet ports or orifices of the Micro-Heart device have “a central, longitudinal axis angled no greater than about 35° in respect to a central, longitudinal axis,” as described on page 2, lines 25-26, such that the discharge from the outlets or orifices is oriented “in an axial direction, or at an angle no greater than 35 degrees off axis,” as described on page 11 at lines 18-20 and illustrated in Fig. 2B. Further, the reference to “outlet ports [that] are configured to provide ‘side firing’ fluid jets or streams” on page 2 of Micro-Heart at lines 29-30 merely refers to the deflected pattern from an axially oriented outlet or orifice that is shown in Fig. 6B and described on page 12 of Micro-Heart at lines 3-4. Thus, rather than being on a sidewall and oriented generally laterally, the Micro-Heart orifices are on the distal end face and oriented generally axially. Accordingly, Micro-Heart does not disclose a device having at least one injection orifice on a sidewall of the end effector wherein the at least one injection orifice is oriented generally laterally to the longitudinal axis of the end effector, as described and claimed in the present application.

Further, amended claim 1 recites a rigid end effector that has a longitudinal axis configured into a shape wherein the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use. A “rigid” end effector is distinct from a “malleable and/or manipulatable” end effector, which may be adapted “to form around or within anatomical structures” during use, as discussed on page 12 of the specification of the present application. In particular, in a malleable and/or manipulatable end effector, the shape of the longitudinal axis may be manipulated during use such that the end effector may be steered or guided around or within anatomical structures during some laparoscopic, thoracoscopic, or arthroscopic procedures. In contrast to a malleable and/or manipulatable end effector, a rigid end effector, as recited in amended claim 1, is sufficiently rigid to maintain the shape of its longitudinal axis during use.

In contrast, Micro-Heart does not disclose, teach, or suggest a device having a rigid end effector that is sufficiently rigid to maintain the shape of its longitudinal axis during use, as recited in amended claim 1. Instead, on page 18 at lines 1-7, as cited by the Examiner, Micro-Heart recites a catheter configured to “maintain the distal tip of the shaft proximate the target region of the endocardial wall.” As described with respect to Fig. 8 in the carryover paragraph on pages 17-18 of Micro-Heart, the catheter resists the “action-reaction forces” caused by a discharge from the distal end of the catheter. However, as used in Micro-Heart, a “catheter” refers to a “steerable catheter shaft or jacket 16 having a controllably deflectable distal-end portion, as at 16a” (page 7, lines 12-

13) that is “dimensioned to be placed in the vasculature of a subject and navigated therethrough until the distal tip is disposed proximate a surface or wall region of a selected tissue or organ” such as an “endocardial wall within the heart’s left ventricle” (page 8, lines 13-16). Thus, rather than being rigid, the Micro-Heart catheter is malleable and/or manipulatable to allow navigation through the vasculature to an endocardial wall, which navigation requires altering or manipulating the shape of the longitudinal axis of the catheter during use. Accordingly, Micro-Heart does not disclose a rigid end effector that is sufficiently rigid to maintain the shape of its longitudinal axis during use, as described and claimed in the present application.

For at least the reasons discussed above, the cited references, alone or in combination, do not disclose, teach or suggest a device as claimed in amended claim 1. Claims 2-10, 21, and 23 contain further limitations that distinguish the cited references. Accordingly, amended claim 1 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 1-10, 21, and 23 under 35 U.S.C. §§ 102 and 103 be withdrawn.

Regarding claims 3 and 23, claim 3 recites that the end effector includes a straight shaft section and claim 23 recites that the shape of the longitudinal axis of the end effector is generally straight. In contrast, Micro-Heart does not disclose, teach or suggest either a straight shaft section or that a longitudinal axis of the end effector is generally straight. Rather, as shown in Fig. 1, Micro-Heart discloses a “steerable catheter shaft or

jacket 16 having a controllably deflectable distal-end portion, as at 16a," which allows navigation through the vasculature, as discussed above. Figs. 2A and 4 of Micro-Heart, as cited by the Examiner, merely illustrate the distal end of the steerable catheter shaft or jacket 16 shown in Fig. 1 of Micro-Heart. Thus, Micro-Heart does not disclose, teach or suggest each and every element recited in either claim 3 or claim 23. For at least these additional reasons, applicant respectfully requests that the rejections of claims 3 and 23 be withdrawn.

Applicant has added new claim 26, which depends from claim 1. Support for the new claim can be found throughout the specification as filed and no new matter is added. Applicant believes that claim 1 is now allowable. Therefore, new claim 26 is allowable for at least the reasons discussed above.

Claim 11 and its Dependent Claims

Claim 11 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Micro-Heart. Claim 24, which depends from claim 11, stands rejected under 35 U.S.C. § 102(b) based on Micro-Heart. Claim 13, which depends from claim 11, stands rejected under 35 U.S.C. § 103(a) based on Micro-Heart. Claims 14-17, which depend directly or indirectly from claim 11, stand rejected under 35 U.S.C. § 103(a) based on Micro-Heart in view of Paskar. Applicant disagrees with the rejections but has nonetheless made certain claim amendments to clarify what Applicant regards as the invention.

Amended claim 11 recites that at least some of the orifices are in a sidewall of the

distal region and oriented in a direction generally lateral to a longitudinal axis of the extension structure. As discussed above, Micro-Heart does not disclose that at least some of the orifices are in a sidewall of the distal region and oriented in a direction generally lateral to a longitudinal axis of the extension structure.

Further, amended claim 11 recites a longitudinally rigid extension structure that is sufficiently rigid to maintain a longitudinal shape during use. A “rigid” extension structure is distinct from a “malleable and/or manipulatable” extension structure, which may be adapted “to form around or within anatomical structures” during use, as discussed on page 12 of the specification of the present application. In particular, in a malleable and/or manipulatable extension structure, the shape of the longitudinal axis may be manipulated during use such that the extension structure may be steered or guided around or within anatomical structures during some laparoscopic, thoracoscopic, or arthroscopic procedures. In contrast to a malleable and/or manipulatable extension structure, a rigid extension structure, as recited in claim 11, is sufficiently rigid to maintain a longitudinal shape during use.

In contrast, Micro-Heart does not disclose, teach, or suggest a device having a rigid extension structure that is sufficiently rigid to maintain a longitudinal shape during use, as recited in amended claim 11. Instead, in Fig. 12, as cited by the Examiner, Micro-Heart discloses “an open surgical tool where device 1200 has an elongated jacket portion 1202” (page 10, lines 7-8). According to the brief description of the drawings on page 7

of Micro-Heart at lines 3-5, Fig. 12 “illustrates an example of the invention where the device is combined with a a [sic] first steerable catheter in one structure which resides in a second steerable catheter.” As discussed above, Micro-Heart equates “jacket” with steerable catheter at page 7, lines 12-13. Thus, rather than being rigid, the elongated jacket portion 1202 disclosed in Fig. 12 of Micro-Heart is malleable and/or manipulatable to allow navigation through the vasculature. Accordingly, Micro-Heart does not disclose a rigid extension structure that is sufficiently rigid to maintain a longitudinal shape during use, as described and claimed in the present application.

For at least the reasons discussed above, the cited references, alone or in combination, do not disclose, teach or suggest a device as claimed in amended claim 11. Claims 13-17 and 24 contain further limitations that distinguish the cited references. Accordingly, amended claim 11 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 11, 13-17 and 24 under 35 U.S.C. §§ 102 and 103 be withdrawn.

Claim 14 recites that at least some of the injection orifices are arranged along the length of the extension structure. In contrast, Micro-Heart does not disclose, teach or suggest that injection orifices are arranged along the length of the extension structure. The reference to “outlet ports [that] are configured to provide ‘side firing’ fluid jets or streams” on page 2 of Micro-Heart at lines 29-30 merely refers to the deflected pattern from an axially oriented outlet or orifice that is shown in Fig. 6B and described on page

12 of Micro-Heart at lines 3-4. Thus, Micro-Heart does not disclose, teach or suggest each and every element recited in claim 14. For at least these additional reasons, applicant respectfully requests that the rejection of claim 14 be withdrawn.

Claim 15 recites that the injection orifices are arranged along the length of the extension structure. In contrast, as discussed above, Micro-Heart does not disclose, teach or suggest that injection orifices are arranged along the length of the extension structure. Thus, Micro-Heart does not disclose, teach or suggest each and every element recited in claim 15. For at least these additional reasons, applicant respectfully requests that the rejection of claim 15 be withdrawn.

Claim 18 and its Dependent Claims

Claim 18 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Micro-Heart (WIPO publication WO 00/72908). Claims 19 and 20, which depend directly or indirectly from claim 18, stand rejected under 35 U.S.C. § 103(a) based on Micro-Heart in view of Kollias et al. (U.S. Patent No. 6,251,099). Applicant disagrees with the rejections but has nonetheless made certain claim amendments to clarify what Applicant regards as the invention.

Amongst other structure, amended claim 18 recites at least one injection orifice on a sidewall of the end effector wherein the at least one injection orifice is oriented generally laterally to the longitudinal axis of the end effector. As discussed above, Micro-Heart does not disclose, teach, or suggest a device having at least one injection

orifice on a sidewall of the end effector wherein the at least one injection orifice is oriented generally laterally to the longitudinal axis of the end effector, as recited in amended claim 18.

Further, amended claim 18 recites a rigid end effector that has a longitudinal axis configured into a shape wherein the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use. As discussed above, Micro-Heart does not disclose, teach, or suggest a device having a rigid end effector that is sufficiently rigid to maintain the shape of its longitudinal axis during use, as recited in amended claim 18.

For at least the reasons discussed above, the cited references, alone or in combination, do not disclose, teach or suggest a device as claimed in amended claim 18. Claims 19-20 contain further limitations that distinguish the cited references. Accordingly, amended claim 18 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 18-20 under 35 U.S.C. §§ 102 and 103 be withdrawn.

Applicant has added new claims 27-28, which depend from claim 18. Support for the new claims can be found throughout the specification as filed and no new matter is added. Applicant believes that claim 18 is now allowable. Therefore, new claims 27-28 are allowable for at least the reasons discussed above.

Conclusion

Applicant believes that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, Applicant respectfully requests that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-1540.

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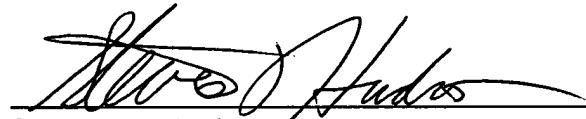
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on March 23, 2006.



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